

### REMARKS/ARGUMENTS

Claims 43-65 are active. The claims have been revised for clarity as suggested by the Examiner. Claims 43, 46 and 54 have been revised to remove redundant terms. Claim 56 has been revised to be in independent form, since it was only objected to as depending from a rejected base claim, but not otherwise rejected. This claim as amended is now in condition for allowance. No new matter has been added. Favorable consideration of this Amendment and allowance of this case are respectfully requested.

### Restriction/Election

The Applicants previously elected with traverse **Group VI**, claims 30-33, directed to a process for purifying DFA III solution. Claims 1, 4-6, 13-26, 29 and 35-42 were withdrawn from consideration. The requirement has been made FINAL. The Applicants respectfully request rejoinder of any claims that cover subject matter encompassed by the nonelected groups depending from or otherwise including all the limitations of an allowed elected claim, upon an indication of allowability for the elected claim, see MPEP 821.04.

### Objection—Claims

Claims 43, 54, and 56 were objected to for various informalities or in the case of claim 56 as depending from a rejected base claim. These objections are now moot.

### Rejection—35 U.S.C. §112, second paragraph

Claims 43-53 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is moot in view of the amendment above.

Rejection—35 U.S.C. §103(a)

Claims 43, 45, 47-55 and 57-59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka, JP 49-117688 (English abstract, “AP” or English translation “N”), Uchiyama, U.S. Patent No. 5,057,418 or Tomita (N), and in view of Saito, et al., Biosci. Biotech. Biochem. 64:3121 and Armarego, Purif. Lab. Chem. 4<sup>th</sup> ed., Ch. 1, pages 1-3. The Applicants refer to their prior arguments and as suggested at the bottom of page 10 of the OA, attach herewith a Declaration under 37 C.F.R. §1.132 containing the experimental data provided with their last response showing the surprisingly superior results obtained by the claimed purification methods.

This rejection cannot be sustained because the prior art does not disclose or suggest all the elements of the invention, namely “**powdered activated carbon**” having an average particle size of **15 to 200 microns** as required by independent claims 43 and 54. At the top of page 5 of the specification, the inventors make clear an essential difference between the prior art methods and the invention—the invention uses powdered active carbon, not granular active carbon. As a result, the inventors discovered a way to remove undesirable odors from purified DFA III that the prior art processes using granular active carbon could not. Consequently, the prior art does not disclose all the elements of the invention, nor suggest using powdered active carbon instead of granular active carbon, nor provide a reasonable expectation of success for the superior results obtained by the invention, namely highly purified DFA III crystals with no odor.

Tanaka, JP 49-117688 (USPTO English translation), page 5, last line, indicates that filtrate is “adsorbed onto an active carbon column”, near the bottom of page 7 it indicates

This liquid is adsorbed onto an active carbon column (column diameter: 2.5 cm, column height: 45 cm; packed with a mixture of 30 g active carbon and 60 g No. 535 Celite with distilled water.

Tanaka does not disclose treatment with activated carbon particles having an average diameter of 15 to 200 microns.

Uchiyama, U.S. Patent No. 5,057,418, col. 5, line 24 and Example 1, col. 6, lines 28-29 refer to processing via a column containing active carbon. This reference also does not disclose activated carbon particles having an average diameter of 15 to 200 microns, nor a step involving treatment with these particles as opposed to processing through a column.

Tomita, JP 03259090 A (“N”), involves use of “activated charcoal and cerite” to purify DFA III, but is also silent about treatment with activated carbon particles having an average diameter of 15 to 200 microns.

Saito was not relied upon as teaching active carbon treatment.

Armarego, “Common techniques used in purification” is a general reference that teaches many purification techniques, including recrystallization using activated charcoal (decolorizing carbon) on page 12. However, Armarego did not disclose treatment with activated carbon particles having an average diameter of **15 to 200 microns**. Further, there is no suggestion in Armarego to apply this method to treatment of DFA III, nor is there any in the other cited prior art which uses column chromatography.

Moreover, as shown by the comparative experimental data below, otherwise identical crude DFA III preparations purified using the invention, which uses activated carbon particles having an average diameter of 15 to 200 microns, lack odor and had superior transparency, to DFA III purified by column chromatography using large particles (1,000  $\mu\text{m}$ ) of active carbon or no active carbon at all.

The Table below, supported by the attached Declaration, shows the average score for each of Samples A, B and C.

	Color average score of expert panel	Smell average score of expert panel
Sample A (invention; average size of active carbon particles ~35 $\mu\text{m}$ )	2.95	2.80
Sample B (granular active carbon; average size of active carbon particles = 1,000 $\mu\text{m}$ )	2.05	2.20
Sample C (no active carbon)	1.00	1.00

These results demonstrate the superiority of the DFA-III product made using the invention. Sample A produced by the method of the invention had a **295%** better color and **280%** better odor in comparison to Sample C which had no active carbon added. Moreover, in comparison to Sample B, which used granular active carbon having an average particle size of 1,000  $\mu\text{m}$ , Sample A had a **144%** better color and **127%** better odor. In addition to the testing results shown in the table above, 19 out of 20 expert panelists rated Sample A as having no color and 16 out of 20 rated it as having no odor. The prior art does not provide a reasonable expectation of success for DFA-III with the superior color and lack of odor provided by the claimed invention. Accordingly, for all of the reasons above, this rejection cannot be sustained.

Conclusion

In view of the amendments and remarks above, the Applicants respectfully submit that this application is now in condition for allowance. An early notice to that effect is earnestly solicited.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Thomas M. Cunningham", is written over a horizontal line.

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